REGISTER OF ACTIONS

CASE NO. D-101-CV-2021-00377

State of New Mexico ex rel, et. al., v. Gilead Sciences Inc, et. al. §§§§§§

Case Type: **Civil Violations, Statutes, Ordinances**
Date Filed: **02/24/2021**
Location:
Judicial Officer: **Sanchez-Gagne, Maria**

PARTY INFORMATION

		Attorneys
Defendant	**Bristol Myers Squibb a Delaware Corporation**	
Defendant	**Gilead Sciences Inc a Delaware Corporation**	
Defendant	**Gilead Sciences LLC a Delaware Limited Liabilty Company *Formerly Known As* Bristol Myers Squibb and Gilead Sciences LLC**	
Defendant	**Teva Pharmaceuticals USA Inc a New Jersey Corporation**	
Plaintiff	**Balderas, Hector H**	**Marcus J. Rael, Jr.** *Retained* 505-242-2228(W) Brian L. Moore *Retained* 505-717-3511(W) P. Cholla Khoury *Retained* 505-827-7484(W)
Plaintiff	**State of New Mexico ex rel**	**Marcus J. Rael, Jr.** *Retained* 505-242-2228(W) Brian L. Moore *Retained* 505-717-3511(W) P. Cholla Khoury *Retained* 505-827-7484(W)

EVENTS & ORDERS OF THE COURT

OTHER EVENTS AND HEARINGS

02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count I - Violation of New Mexico Anti Trust Act Against Gilead and Teva)
	Action Type	Action
02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count II - Violation of New Mexico Anti Trust Act Against Gilead, BMS and Gilead-BMS JV)
	Action Type	Action
02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count III - Violation of New Mexico Anti Trust Act Against Gilead Only)
	Action Type	Action
02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count IV - Violation of New Mexico Anti Trust Act Against Gilead Only)
	Action Type	Action
02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count V - Violation of New Mexico Anti Trust Act Against Gilead and Teva)
	Action Type	Action
02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count VI - Violation of New Mexico Anti Trust Act Against Gilead, BMS and Gilead-BMS)

EXHIBIT A

	Action Type	Action
02/24/2021	**Cause Of Actions**	Statutes, Ordinance Violations, Miscellaneous (Count VII - Violation of New Mexico Anti Trust Act Against All Defendants)
	Action Type	Action
02/24/2021	**OPN: COMPLAINT**	
	Complaint for Violations of New Mexico's Anti-Trust Act and Unfair Practices Act	
03/17/2021	**Summons**	
	Bristol Myers Squibb	Unserved
03/17/2021	**Summons**	
	Gilead Sciences Inc	Unserved
03/17/2021	**Summons**	
	Gilead Sciences LLC	Unserved
03/17/2021	**Summons**	
	Teva Pharmaceuticals USA Inc	Unserved
03/17/2021	**ENTRY OF APPEARANCE**	
	Entry of Appearance for Marcus J. Rael, Jr.	
03/17/2021	**JDG: JUDGE EXCUSAL/PEREMPTORY CHALLENGE** (Judicial Officer: Sanchez-Gagne, Maria)	
	Notice of Peremptory Excusal xc: LW	
03/18/2021	**JDG: JUDGE UNTIMELY EXCUSAL**	
	Case has not been reassigned due to untimely filing of Peremptory Excusal	

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

STATE OF NEW MEXICO, *ex rel.* HECTOR H. BALDERAS, Attorney General,

Plaintiff,

v.

GILEAD SCIENCES, INC., a Delaware Corporation, GILEAD SCIENCES, LLC (f/k/a BRISTOL-MYERS SQUIBB & GILEAD SCIENCES, LLC), a Delaware Limited Liability Company, BRISTOL-MYERS SQUIBB, a Delaware Corporation, and TEVA PHARMACEUTICALS USA, INC., a New Jersey Corporation,

Defendant.

Case No. D-101-CV-2021-00377
Case assigned to Sanchez-Gagne, Maria

JURY TRIAL DEMANDED

COMPLAINT FOR VIOLATIONS OF NEW MEXICO'S ANTI-TRUST ACT AND UNFAIR PRACTICES ACT

COMES NOW Plaintiff, the State of New Mexico, by the Honorable Hector Balderas, Attorney General of the State of New Mexico ("Plaintiff" or "State"), and brings this action against defendants GILEAD SCIENCES, INC. ("Gilead"), BRISTOL-MYERS SQUIB ("BMS"), GILEAD SCIENCES LLC f/k/a BRISTOL-MYERS SQUIBB & GILEAD SCIENCES, LLC ("Gilead-BMS JV"), and TEVA PHARMACEUTICALS USA, INC. ("Teva") (collectively "Defendants"). In support of its Complaint, the State avers as follows:

I. INTRODUCTION

1. Plaintiff, by and through its Attorney General, Hector Balderas, brings this civil action to redress unlawful and deceptive practices, to obtain declaratory and equitable relief, restitution, statutory penalties and all damages recoverable at law or in equity to remedy Defendants' willful and deliberate violations of the New Mexico Anti-Trust Act, NMSA 1978, Sections 57-1-8 to -19, ("NM Anti-trust Act") and the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 to -22, ("NM UPA")).

2. This action arises out of Defendants' long-running fraudulent and coordinated schemes, improper restraints of trade, and unfair and deceptive business practices that have effectively curtailed generic competition, resulting in excessively inflated pricing for crucial antiretroviral medications used in the prevention and treatment of Human Immunodeficiency Virus ("HIV") – a disease which, if left untreated, destroys the immune system, and leads to Acquired Immunodeficiency Syndrome ("AIDS"). The antiretroviral medications at issue include Gilead's VIREAD® (tenofovir disoproxil fumarate ("TDF")) and generic versions of same, TRUVADA® (a combination of Viread (TDF) and emtricitabine ("FTC")), ATRIPLA® (a combination of Truvada (TDF and FTC) and efavirenz ("EFV")), (collectively referred to as "TDF-Based"), as well as Gilead's VEMLIDY® (tenofovir alafenamide fumarate ("TAF")) and DESCOVY® (TAF

and FTC) (collectively referred to as "TAF-Based"). Each of these HIV Medications[1] consists of one or more component drugs of the nucleotide/nucleoside analogous reverse transcriptase inhibitor ("NRTI") class, which include tenofovir disproxil fumarate ("TDF"), tenofovir alafenamide fumarate ("TAF"), and emtricitabine ("FTC"). The following chart summarizes each branded drug and its component drugs:

Branded Drug	1st NTRI	2nd NRTI	Third Agent
VIREAD®	TDF		
TRUVADA®	TDF	FTC	
ATRIPLA®[2]	TDF	FTC	EFV[3]
VEMLIDY®	TAF		
DESCOVY®	TAF	FTC	

3. Gilead owns the patents (or has obtained exclusive licenses to the technology) for the component drugs TDF, TAF and FTC, as well as patents for the branded drugs Viread, Truvada, Atripla, Vemlidy and Descovy. As each drug's patent was challenged or set to expire, Gilead entered into unlawful, deceptive and anticompetitive arrangements with BMS, Teva and other unnamed entities to delay and suppress entry of cheaper generic versions of each drug. The net result of Gilead's and other Defendants' unlawful actions resulted in unwarranted and excessively over-priced HIV Medications costing the State millions of dollars in drug reimbursements.

[1] "HIV Medications" include Viread, Truvada, Atripla, Vemlidy, Descovy and any generic versions of same.
[2] Atripla was marketed by Gilead Sciences LLC, a joint venture between Gilead and BMS, and is currently marketed solely by Gilead.
[3] Efavirenz ("EFV"), known by trade name SUSTIVA®, is commercialized by BMS.

4. HIV is one of the deadliest human pandemics in history. Since the first cases were reported in the summer of 1981, more than 700,000 people United States ("U.S.") and 35 million worldwide, have perished from the disease. In the United States, the HIV epidemic is still ongoing. The Centers for Disease Control and Prevention ("CDC") reported that in 2017, the last year for which data is available, an estimated 1.1 million people in the U.S. were living with HIV, nearly 40,000 people were newly diagnosed with it, and more than 5,000 Americans perished from it.

5. U.S. government payors, including State Medicaid programs, are one of the single largest sources for insurance coverage and accessibility to antiretroviral medications for people living with HIV.[4] State Medicaid reimbursements for Gilead's HIV Medications are also a primary source of Gilead's profits, as Gilead sells its HIV Medications in the U.S. at exponentially higher prices compared to other countries around the world, where pricing is much closer to the cost of manufacturing. By way of example, several of Gilead's HIV Medications cost less than $10 to produce, yet for years Gilead has been able to consistently charge U.S. government payors over one thousand dollars for a 30-day supply.[5]

6. Improved access to antiretroviral therapies ("ART") that durably suppress the virus prevents the development of AIDS in persons living with HIV and decreases the likelihood of transmission of HIV to others. Current HIV treatments are highly effective, but not curative. Available treatments help people with HIV live longer, healthier lives, but do not eliminate the virus from the human body or prevent reemergence of the virus when the treatment is discontinued.

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[4] *See* Kaiser Family Foundation, Medicaid and HIV, (Oct. 1, 2019), available at: https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/ (last accessed Aug. 26, 2020).

[5] In 2017, Gilead charged on average $1,500 for a 30-day supply of Truvada and $1,028 for a 30-day supply of Viread. Of note, Truvada costs less than $9 to produce. Centers for Medicare & Medicaid Services ("CMS"), National Average Drug Acquisition Cost Database, https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-as-of-2017-07-26/yv6n-8hzz (last accessed Aug. 26, 2020).

Access to affordable HIV medications is an absolute necessity to preventing infections and maintaining treatment for those living with HIV.

7. As drug-resistant strains of HIV continue to rise, today treatment strategies often combine multiple ART from different drug classes, also known as ("cART"). The backbone for most cART regimes typically consists of NRTIs, which function as analogs of the naturally occurring deoxynucleosides and deoxynucleotides needed to synthesize the viral DNA. Thus, they can disrupt the reverse transcription process needed to generate the HIV DNA, thereby preventing integration of the proviral DNA into the genome of human cells.

8. During all times relevant, Gilead was the exclusive maker, and/or remains the dominant maker, of TDF and TAF – two of the principal NRTIs used in any cART regime. TDF and TAF are prodrugs of the same parent molecule tenofovir and are similar in structure. Prodrugs are pharmacologically inactive compounds that, once administered, undergo a conversion by the body's metabolic processes to become an active pharmacological agent.

9. TDF and TAF are almost always used alongside another NRTI, specifically either FTC or lamivudine ("3TC"). When an HIV virus becomes resistant to either FTC or 3TC, the virus's susceptibility to TDF and TAF increases. Thus, the combination of TDF or TAF with either FTC or 3TC makes it more difficult for the virus to develop resistance to a cART regimen.

10. FTC and 3TC are remarkably similar, varying by the substitution of only a single hydrogen atom in 3TC, with a fluorine atom in FTC in the 5-prime position of the cytosine ring. Both the U.S. Department of Health and Human Services ("HHS") and the World Health Organization ("WHO") guidelines stipulate that the drugs, when used for HIV treatment, can be used interchangeably. Any cART regimen using FTC can use 3TC instead, and vice versa, without a reduction in therapeutic efficacy.

11. The ability to use 3TC instead of FTC is important to the antitrust claims here. Gilead owns and currently still has patent protection for FTC, but generic 3TC has been available in the U.S. since 2012. Thus, when generic TDF became available in December 2017, the price of cART regimens should have dropped precipitously because two generic NRTIs—3TC and TDF—were available in the marketplace. This complaint outlines how Gilead and its co-conspirators prevented those price drops from occurring.

12. Gilead deliberately and deceitfully delayed generic competition of life-saving TDF-Based products, including Viread, Truvada and Atripla, for years through sham patent litigation against generic manufacturers and by entering into anticompetitive settlement agreements with Teva (as well as other generic manufacturers). As a result, Gilead and Teva, individually and collectively, were able to retain hundreds of millions of dollars in anticompetitive profits at the expense of government payors, like Plaintiff. Defendants engaged in such exclusionary conduct, with full knowledge that the launch of generic versions of TDF-Based HIV Medications would dramatically reduce pricing,[6] to wrongfully insulate themselves from competition, in order to maintain exorbitant pricing and earn outsized profit margins.[7] Defendants' duplicitous actions and unfair business practices directly resulted and continue to result in the State and New Mexico participants paying excessive amounts for TDF-Based HIV Medications.

13. Gilead deliberately and purposefully withheld development and introduction of superior TAF for over a decade in order to extend its monopoly and earn out-sized profit margins on its TDF-Based HIV Medications. Only after generic competition was imminent, did Gilead

[6] *See e.g.,* Gilead Sciences, Inc. SEC Form 10-K 2017 Annual Report ("[s]ales of generic versions of [its] products could significantly reduce [its] sales and adversely affect [its] results of operations.").
[7] *See e.g.,* Gilead Sciences, Inc., Financial Presentation, *Third Quarter Earnings Slides* at 39 (Oct. 27, 2015) (In 2015, Gilead was able to earn an astonishing 90% Non-GAAP Product Gross Margins).

introduce TAF, engaging in a fraudulent and unlawful product-hopping scheme to switch TDF-Based prescriptions to TAF-Based prescriptions.

14. Gilead engaged in deceptive, misleading and fraudulent marketing schemes targeting government payors and healthcare providers ("HCPs") to switch patients from its HIV Medications facing generic competition (and thus reduced pricing) to higher-cost HIV Medications purportedly protected by weak evergreened and ancillary patents and/or protected from competition through unfair business arrangements with BMS shielding products from generic competition. Such marketing schemes were employed to deceitfully induce prescriptions for and switches to Gilead's HIV Medications.

15. In connection with these unfair settlement agreements, collusive collaborations and product-hopping schemes, when faced with imminent generic competition, Gilead would unfairly increase the already exorbitant pricing for its HIV Medications to wring the last bit of available profits from its HIV franchises. As a result, Medicaid reimbursements for Gilead's HIV Medications have substantially increased over time. In 2012 the State reimbursed over $2 million for Gilead's HIV Medications, that number increased to $5.8 million in 2014 and $7.3 million by 2016.

16. One of Gilead's most lucrative and shameless product-hopping and deceptive marketing schemes involves Truvada and Descovy, which are used as a pre-exposure prophylaxis ("PrEP") - one of the most effective ways to prevent infections in individuals not currently diagnosed with HIV. The use of PrEP is of the utmost importance to public health and PrEP

medications are indispensable in terms of ending the HIV/AIDS epidemic in the U.S. As a result, Truvada for PrEP is covered in all respective State Medicaid programs.[8]

17. Gilead has unfairly profited from taxpayer dollars that funded government clinical research for the use of Truvada and Descovy in a PrEP regime. After Truvada's initial approval, the government took it upon itself to conduct clinical research and obtain patents covering the use of tenofovir, including both TDF and TAF, in a PrEP regime. Gilead relied on the government's research and patents in its submissions to the FDA to gain approval for a PrEP indication for Truvada.

18. Gilead has clearly benefitted from the government's patents and research as the use of Truvada and Descovy for PrEP have sky-rocketed (along with its sales). Yet, to date, Gilead has not fairly obtained a license to the government's patents or paid reasonable royalties to the government for its ground-breaking PrEP research. Instead, Gilead implemented another deceptive product-hopping marketing scheme to switch prescriptions from Truvada, now facing imminent generic competition and lower pricing, to Gilead's patent protected TAF-Based Descovy, in order to keep prices artificially high and maintain its inflated profit margins. Gilead's unconscionable business practices drastically reduce access to crucial preventative HIV Medications at the expense of government payors, like Plaintiff, and to the detriment of public health.

19. Defendants' unlawful settlement agreements, unfair and anti-competitive conspiracies and coordinated efforts to limit competition to maintain sky-high pricing and profits, along with Gilead's deliberate deception and fraudulent product-hopping and marketing schemes, targeting HCPs and participants reimbursed under the State's Medicaid Program, knowingly

[8] *See* N. Seiler, *Leveraging Financing and Coverage Benefits: Medicaid Strategies to Deliver PrEP Intervention Services,* ACADEMY HEALTH (Jan. 2019).